REMARKS

Prior to consideration of the substantive arguments below, applicants respectfully request that this application be transferred to the appropriate Art Unit for examination of the disclosed and claimed subject matter. As discussed below, applicants believe that transfer of this application would promote consistency in examination of claims directed to antisense oligonucleotides and would allow applicants to obtain a full hearing by an Examiner experienced in this art.

The reasons for requesting transfer are as follows:

1. Enablement standard under 35 U.S.C. § 112, first paragraph. The present Examiner has twice rejected claims to antisense oligonucleotides on the grounds that "gene therapy using antisense molecules" is unpredictable (Advisory Action dated April 7, 2004, page 12). Applicants previously argued that the alleged unpredictability of gene therapy is an inappropriate standard for assessing enablement of claims to antisense oligonucleotides. As discussed in Section 2 following, applicants submit that defining antisense oligonucleotides as agents of gene therapy is inappropriate for examination purposes.

2. Antisense oligonucleotides are not classified as "genetic material." The Patent Office Classification System classifies antisense technology in Class 435/375. The classification guidelines indicate that antisense oligonucleotides are not to be classified with polynucleotides that function as genetic material within the cell. Examples of text from the classification guidelines are as follows:

(a) 435/455 covers "Introduction of a Polynucleotide Molecule or Rearrangement of Nucleic Acid within an Animal Cell." As stated at Note 5 for this class/subclass, "Neither antisense oligonucleotides nor catalytic RNA molecules function as genetic material within cells." Introducing an antisense oligonucleotide into a cell appears to be excluded from this class/subclass.

(b) 435/440 covers "Process of Mutation, Cell Fusion or Genetic Modification," and Note 4 states, "a transient change is one which is passing or of short duration. Methods of producing nongenetically encoded changes effected by a nucleic acid molecule, such as antisense nucleic acid, are not proper for this and indented subclasses." This class/subclass

covers incorporating genetic material from an outside source, and producing a transient change in the genotype of a cell using genetic material from an outside source.

(c) 435/471, Note 4, states "Neither antisense oligonucleotides nor catalytic RNA molecules function as genetic material (i.e., do not encode genetic information) within cells."

These classification guidelines further state that 435/375 is the correct classification of antisense oligonucleotide applications (except treatment of microbial cells, subclass 243+). Thus, the Patent Office classification system clearly excludes antisense RNA from functioning as genetic material, or from causing a genetically-encoded change, for purposes of examination. The guidelines appear to preclude examination of antisense RNA in terms of a function as a "gene therapy" polynucleotide. Thus, applicants question the Examiner's reliance on enabling a "gene therapy" utility of an antisense oligonucleotide in examining the present application.

3. The Examiner required election of one species of antisense, contrary to the practice in Art Unit 1635. In a restriction requirement dated October 2, 2002, the Examiner required applicants to elect one species of antisense oligonucleotide from among SEQ ID NO:1, 3 and 5. (SEQ ID NO:1, 3 and 5 hybridize to regions of the only polynucleotide that is the subject matter of the application.) This election requirement is inconsistent with the practice that applicants have encountered in cases examined in the antisense art unit (Art Unit 1635, according to several patents recently issued to applicants), in which more than one antisense oligonucleotide (which hybridize to a single gene) have been examined in one application. Thus, as a result of the examination by the current Examiner, applicants have been required to pursue less subject matter per application than in all other antisense cases prosecuted to date by the applicants. This leads to the potential of shorter patent terms and greater cost of prosecuting antisense oligonucleotides, if examined at a rate of one per application.

For the foregoing reasons, applicants respectfully request that this application be transferred to the appropriate Art Unit for examination of claims directed to antisense oligonucleotides.

Responding to the issues discussed in the Advisory Action, applicants submit that the Branch and Monia references do not in totality support the Examiner's position that the antisense molecules cannot be "envisioned" (page 4, paragraph 3 of Advisory Action). Applicants submit that because the overall theme of the Examiner's position relates to enablement of gene therapy,

compliance with the written description requirement needs to be reassessed without applying a gene therapy utility of antisense molecules. For the same reasons, applicants disagree with the Examiner's conclusions based on the enablement rejection, specifically at page 9, paragraph 3 of the Advisory Action ("these oligonucleotides have no enabled real world use"), referring to use in gene therapy.

Applicants respectfully request reconsideration of the claims, without applying standards of gene therapy as the utility, to determine whether the requirements of 35 U.S.C. § 112, first paragraph, have been met. Finally, applicants also respectfully request reconsideration of the restriction requirement in which only one species of antisense molecule (SEQ ID NO:1) was examined in this application. The Examiner is invited to contact the undersigned representative if a telephone conference would aid in resolving any issues related to the application.

All of the claims remaining in the application are now clearly allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

If questions remain regarding this application, the Examiner is invited to contact the undersigned at (206) 628-7650.

Respectfully submitted,
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